United States Court of Appeals

for the Second Circuit

APPELLANT'S BRIEF & APPENDIX

UNITED STATES COURT OF APPEALS SECOND CIRCUIT

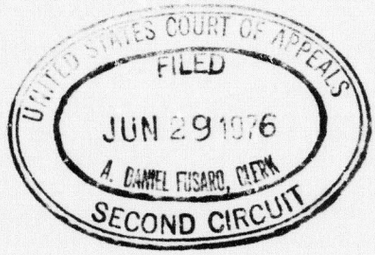
C. A. TEMP: NO. T-6079

76-7298

MR. JOHN L. GRADY
MRS. FATIMA GRADY
PLAINTIFFS

VS.

DR. RODERICK A. McLEAN
DEFENDANT



JUN 29 1976

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APPEAL: PETITION FOR REVIEW

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT

OF NEW YORK

BRIEF OF APPELLANT:

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REPRESENTATIVE: (John L. Grady)

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UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

C.A. TEMP. NO. T-6079

MR. JOHN L. GRADY,
MRS. FATIMA GRADY,
Plaintiffs

VS.

" BRIEF OF THE APPELLANT "

DR. RODERICK A. McLEAN,
Defendant.

STATEMENT OF CASE-IT'S NATURE:

This case was commenced on February 10, 1976, by the filing of a complaint with the Clerk of the U.S. District Court, Northern District Of New York, Utica, New York. The original complaint was held up in Office of the U.S. Marshal by request of the plaintiffs, for the purpose of filing an amended complaint as a matter of course. The amended complaint was filed with the Clerk of the District Court, Utica, New York, on February 23, 1976, and the complaint and the summons with other required papers, were filed, and given together to the U.S. Marshal's Office for service on February 23, 1976.

However, the defendant appeared to be away! on vacation, therefore, he was not served until he was found, and then served on March 31, 1976. Since the plaintiffs were not dilatory on their part in following the Federal Rules Of Civil Procedure in accordance to Law, the plaintiffs were not, and is not aggreived over the service process of the summons, and waives argument of same.

No Responsive Pleading is received by plaintiffs; as defined under Rule 5(e), F.R.C.P.. The defendant's answer was a required one from the evidence on the cover sheet, served with the summons. Therefore, since the defendant's answer was a written motion of affidavit; similar papers from the District Clerk's Office should have been served upon each of the parties. However, this rule was not followed, for the plaintiffs did not receive a copy of the defendant's answer from the Clerk's Office even as yet. If under Rule 5(e), F.R.C.P., an exception was made by a Judge, permitting the defendant's attorney to file his answer with him, then Rule 12(a), F.R.C.P. again comes into play as follows: The service of a motion permitted under this rule alters these periods to time as follows, unless a different time is fixed by order of the Court: (1) if the court denies the motion or postpones its disposition until the

" BRIEF OF THE APPELLANT "

STATEMENT OF CASE - IT'S NATURE:

trial on the merits, the responsive pleading shall be served within 10 days after notice of the Court's action. However, if no responsive pleading was allowed, then Rule 15a, F.R.C.P. last paragraph comes into play: " A party shall plead in response to an amended pleading within the time remaining for response to the original pleading or within 10 days after service of the amended pleading, which ever period may be the longer, unless the Court otherwise orders. The plaintiffs herein claims that the defendant defaulted, for it was past 10 days when his reply was received, as evidenced in item (b) in addendum. There is no evidence in the docketed enteries from the lower court records, indicating that the Court had fixed any different time, prior to the reception of item of exhibit (b) by the plaintiffs, see item of exhibit(b) in addendum.

From the above evidential facts in this case; if the Judge did render hid Judgement Order for Dismissal until the trial on the merits, and this trial on the merits have not come as yet! either; the responsive pleading should have been within 10 days under Rule 12a, F.R.C.P.; Or the case was dismissed less the hearing, or taking into consideration any facts pleaded by the plaintiffs, other than the short original statement found on the face of the complaint relative to federal question.

However, the defense attorney mailed the plaintiffs an Original Affidavit of Answer, or reply,(see exhibit(b) in addendum, the plaintiffs did not receive any copy at the time, or ever, from the Clerk's office of the defendant's reply. But, the notice required the plaintiffs to appear on May 10, 1976, at Federal Bldg., Clinton St. Syracuse, N.Y., which resulted in the dismissal of the complaint on the grounds of lack of subject matter jurisdiction.

The plaintiff's claim for damages was filed as; a gross negligent liability under federal statute, it was a breach of duty owed under federal regulations(FDA), or a violation of the plaintiff's Federal Rights under the U.S. Constitution, and Statute. The Constitutional provision is derived from the " commerce clause ",(Art.1, Sec. 8, cl.3) that grants to Congress the power to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.

STATEMENT OF FACTS RELEVANT TO ISSUE PRESENTED FOR REVIEW:

The Federal power to regulate interstate commerce - is concurrent with state power over transactions occuring within the state. Because of this overlapping of power, the Court is called upon to determine the scope of federal power Vs. state power in the regulation of commerce. In the case at hand, the defendant did not comply with applicable rules, or standards of safety regulations of,

STATEMENT OF FACTS RELEVANT TO ISSUE PRESENTED FOR REVIEW:

safe dispensing of the experimental drug Provera was at that time. The required conduct of the defendant fell short of the duty of care owed, or required by the labeling under the Food and Drug Administration, under the Food Drug and Cosmetic Act., U.S.C. Title 21, and Subchapter 7, General Administrative Provisions Section 371-355 under authority of the Health Education and Welfare; who agrees that the Doctor is the proper person for providing use information to his patients, and that the doctor recognizes an obligation to discuss the potential hazards of taking the drug, and again this the defendant did not do.(see exhibit 4, in the records, page 2).

The defendant is charged with, and is liable under the law for breaching stipulated rules of safety under experimental drug labeling, and of the plaintiff's federal rights.

Under chapter one of the Federal Register, F.D.A. Section 310.501, (see item 4, from the records), the F.D.A. is charged with assuring both doctor and patient that drugs are safe, and effective for their intended uses. However, this assurance can go no further than the safe labeling requirments given under each circumstance, of an experimental drug, which is under federal regulation, and if this assurance is breached, the responsibility lies with the breacher, when licensed to dispense such drug, for the full disclosure of information given to the doctor, such as; Warnings, Precautions, and Adverse reactions, is his important element in the discharge of his responsibility under the federal law. The doctor's responsibility is transferred by the FDA Regulations, making him responsible, or liable for any act of negligent conduct. However, at no time is the plaintiff's federal protective rights transferred, for they remain under federal law.

The safety rules under labeling is found in item 6, of the lower court records,(see item 6, under precautions-pretreatment, the required safe rules to be followed by the dispenser of this drug). The defendant omitted these safe rules, thereby causing the plaintiff to be injured more, in addition to her already health problem, presented to the defendant on her initial visit to his office, from this doctor's lack of care in following the federal regulations of safety. For it was!!- under the statute that these rules of safety measures are required in dispensing experimental drug as; Medroxyprogesterone Acetate during September 5, 1973.

This drug has been under study since 1965. In July of 1963, a notice of claimed investigational exemption for a new drug (IND), was submitted to the Food and Drug Administration providing for clinical studies, to investigate the drug's safety and efficacy in contraception. These

STATEMENT OF FACTS RELEVANT TO ISSUE PRESENTED FOR REVIEW:

studies were started in February of 1965, the exemption meant that a privilege was allowed for testing of the drug, which was an incomplete kind of approval by the FDA(see item 1, column one, from the lower court records), this certainly verifies the fact that the drug was in an experimental stage, automatically giving more credence to the charge of the defendant's breach, of care to the plaintiffs under this regulation.

A notice published in the Federal Register dated July 27, 1972(27- FR-15033), the Commission of Food and Drug announced his conclusions pursuant to an evaluation of a report received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on Depo Provera Sterile Aqueous Suspension containing medroxyprogesterone acetate; The Upjohn Co., 7171 Portage Road, Kalamazoo, Michigan 49001. The July 27th, notice stated; that medroxyprogesterone acetate administered intramuscularly is probably effective for endometriosis which is characterized by ovarian cysts. Therefore, notice was given to the holder of the new drug application, that the Commissioner proposed to issue an order under section 505(e) of the Federal Food, and Cosmetic Act.(21 U.S.C. 355(e), under number (1) of this section, the Secretary found that clinical experience, tests, or scientific data showed that such drug is unsafe for use under the conditions of use upon the basis for which the application was approved, therefore it was a new drug. (2) it was found to be unsafe for specific uses as claimed, (4) the drug was not found to be effective for it uses, and the Secretary found that the drug application contained untrue statement of material fact, and that there was an imminent hazard to the public health. All identical related, or similar products, not the subject of an approved new drug application at the time; as oral provera tablets etc., are covered by the new drug application reviewed, Section 21 CFR 130.40 (37 FR 23185, Oct. 31, 1972).(see item 2, from the records paragraph 3, last part of column).

These studies are given by the administration of research grants projects in the program, of the U.S. Department Of Health Education and Welfare -318. The Food and Drug Administration(FDA) activities are directed toward protecting the health of the nation, against unsafe drugs, and other potential hazards such as; the disregarding of safe rules, and precautionary rules treatment, and warnings, while the drug is yet in it's experimental stage; by those doctors who are responsible for safe administration.

The Bureau of Biologics administers regulations of biologic products shipped in interstate commerce; and establishes written and physical standards. The Bureau of Drugs develops standards-conducts with respect to

STATEMENT OF FACTS RELEVANT TO ISSUE PRESENTED FOR REVIEW:

efficacy, reliability, and safety.(see item 5, as contained in the district court records).

The Commissioner under Title 21 Food and Drug, Section 310.501, has concluded that it is necessary that information in lay language, concerning effectiveness, contradictions, warnings, precautions, be discussed by the doctor before dispensing provera; is the important element, and is within the public interest. Under section 310.502 Food and Drug Administration, paragraph 5, a statement of the need for special supervision of patients with possible fibroids of the uterus, or those having special health problems as the plaintiff's is, the doctor is given the option to determine if it is safe for use. However, in order that the doctor's determination that is required by the regulation is safely determine, he must follow the safe rules, if he refuses to do so? Then he has breached the patient's federal protective rights under the statute in the case of experimental drugs when injury results.

Warnings,Precautions, Consent, even though not optional if disregarded presents a liable conduct on the doctor's part, but the plaintiff's federal rights are never transferred, or can be made optional, for this right is protected by the health clause under the federal regulation.

In checking item No.1, page 2, from the records, paragraph 3, it is quoted: " If you now have or have had a special health problem such as migraine headaches, mental depression, fibroids of the uterus,, heart or kidney disease, asthma, high blood pressure, diabetes, or epillepsy, report these facts to your physician so that he may determine if it is safe for you take (incert-trade name of drug). All of these conditions could sometimes,could be made worst by the use of this medication." Therefore, in the complaint the plaintiffs charged that this medication(medroxyprogesterone acetate), has made the plaintiff's condition worst, and caused more injury to her reproductive organs, for the special health problem of infection in her reproductive organs was known by the defendant, yet he gave this hormone drug that affects many organ systems, and can mask infection, he did not make a pap smear test to determine if the plaintiff had fibroids in her uterus, and when the pap smear test that he made on the same day of his examination, returned; it revealed that the plaintiff had inflammation of her endocervix, and vagina, but the damage had been done by the hormone drug, and the defendant could certainly see the possible damage which could take place with the administration of an unsafe hormone drug which was so labeled with many precautions, and warnings.

There is no excuse for not following the safe rules in determining the condition of the plaintiff's uterus prior to dispensing medroxyprogesterone.

" BRIEF OF THE APPELLANT "

SUBJECT MATTER JURISDICTION:

The defendant's violation as; complete disregard of federal precautionary regulations under the Food and Drug Administration, as deemed under the Food Drug and Cosmetic Act., carried out by the rule making authority of the FDA, as defined under their labeling for precautions of safety while under experimentations, of safety rules for hazardousness, risks,and efficacy, and in this case, where there is evidence that medroxyprogesterone acetate has been taken off the market at times, because of questional risks of safety being involved, until its field studies are complete, and where the patient as the plaintiff; had a prevailing health problem upon initial examination, certainly is sufficient to invoke the judicial power of the U.S. Court.

Pursuant to the above mentioned violation, Congress has acted without doubt, to provide complete regulation, and conventionally, to occupy this field completely because of new drugs, and it's experimentation of the same in relations with interstate commerce.

New drug studies, or experimental stages of the drug Provera in any form, in lay terms; birth control drugs containing progestins, or medroxyprogesterone acetate, while under study, is experimental as law deems it, not a completely approved drug while under study, certainly warranted stricter FDA Rule observance by those administering it.

From reasoning of the facts under statutory inactment of 28 USC Section 1331 Chapter 85, " General Federal Question," pursuant to the Food Drug and Cosmetic Act., Title 21, Section 371, it is certain, and without excessive searching doubt, that Congress intended to dominate the field of National Safety, in regards to applicable law, while in stages of experimentation as was medroxyprogesterone acetate, as seen in item no. 1, from the records of the lower Court.

Even though the Federal Power to regulate commerce among the several states, is within concurrence with State Power over transactions occuring within the state, because if the overlapping of power in regulating such commerce becomes a question of issue, the Court is called upon again to determine the scope of Federal Power Vs State Power in regulating such commerce°, See(O in table of statutes).

The principal issues as to the scope of power under the commerce clause involves two main issues. (1) What constitutes commerce?. (2) What is meant by regulation thereof? Judge Marshall in the case of; Gibbons V. Ogden in the land mark case, gave a very broad definition to commerce, defining it as more than mere traffic, but rather; " any inter-

SUBJECT MATTER JURISDICTION:

course " among states. However, this was limited to transportation.[P], See(exhibit P, in addendum).

The modern view is called the affectation doctrine, today the Court recognizes that Congress has the power to regulate any activity, whether carried on in one state or many, which has any appreciable effect, direct or indirect upon interstate commerce.

The major function of the Court today is in defining the scope of federal commerce power; is one of statutory interpretation which basically is a question of determing Congressional intent: Did Congress intend in regulation to apply to this particular transaction involved, or the case at hand, and to this; the plaintiffs have already shown.

However, the affectation doctrine gives Congress the widest possible scope of power. The Court has recognized this and taken the position that the only effective restraints on Federal Commerce Power is all-pervasive, and any limitations on the power must proceed from political, rather than from judicial processes. The Court won't read in any limitations[O], See(table of cases).

Factors which are considered in determination of Congressional intent: The Court will consider the following facts under conflicts of laws; whether a particular Federal Law was intended by Congress to preempt, the field or subject matter. The dominance of federal interest in the field where the subject matter is one of inherent national interest, it will be assumed that Congress intended to preempt the field, and thus preclude local regulation. The interest in uniformity, and national regulation, this is usually the controlling factor. Therefore, wherever the subject matter is one requiring national regulation the Court is inclined to find that Congress intended to occupy the field completely and supersede state regulation. In such cases State Law is superseded because of conflict with Federal Law, and where the repugnance is so direct and positive that the state and federal regulations cannot be reconciled or consistently stand togather. The repugnance may be in the express provision of the Statutes, but is more frequently encountered in the application and administration thereof. However, no state regulation of any kind is permissible where the subject matter is such that it inherently requires uniform treatment throughout the nation, if regulation on a national scale is required, the matter must! await Congressional action, or the Court's determination.

" BRIEF OF THE APPELLANT "

SUBJECT MATTER JURISDICTION:

There are two contructions where implied remedies to protect the plaintiff's constitutional rights, which gives Federal jurisdiction in this case: Federal Law; stemming from the Food Drug and Cosmetic Act.,Title 21, Subchapter 7, General Administrative Provisions Section 371, 355, under authority of the Secretary Of Health Education and Welfare, that Congress intended under this chapter 21, that all persons in the national domain be protected against injury from dilatory treatment by competent doctors,[n]as in this case, See[n], table of cases.

Therefore, the defendant's duty of care is known by examination of surrounding circumstances, or the actions of the defendant that is known, and implied from the federal duty owed, gives Federal Question Jurisdiction.

The second construction is the determination from the pleadings of the lower court records, which was narrowed by application of a well pleading rule, that the federal question must appear on the face of the complaint well pleaded, which stemmed from the 1875 Statute, conferring General Original Jurisdiction on Federal Questions cases. However, in the complaint of the plaintiffs, it is only required that; a short and plain statement, showing that plaintiffs are entitled to relief, and to demand the relief to which plaintiffs deems themselves entitled, this was set forth, and no more; for the details were to follow in the pleadings, which the merits of, have never been heard until the argument of this evidence to the Court of Appeals, or the date of the decision of dismissal May 10, 1976.

Since jurisdiction for judicial review of Adminsitration action relating to drugs is statutory, initial approval, or exemption of drugs is within primary jurisdiction of the F.D.A., and medroxyprogesterone acetate was unsafe for use at the time of administration in this case of the plaintiff, due to her infection of her reproductive organs at the time of the doctor's prescription, and especially without knowing by laboratory cytologic tests the condition of the plaintiff's uterus, before dispensing provera, which was the breach of duty of safety owed, under federal law.

Relative to State jurisdiction as suggested by the Judge on May 10, 1976, its well to understand that state courts may not award tort damages arising out of allegedly unfair labor practices by union activites which are under the jurisdiction of the of the NLRB, even where the NLRB declines to act, due to potential frustration to national policy by conflicting state determinations as to what constitutes unfair labor practices...this would defeat the objective of the federal statute[1],(see table of cases). In State Court any conflict of interest can affect the plaintiff's rights to relief.

" BRIEF OF THE APPELLANT "

THE ARGUMENT SUMMARY:

Plaintiffs argue and show proof of the facts contained on the face of the complaint; that entitles them to relief, for the act comes under a statute, and is breached by the conduct of the defendant, as a breach of duty of care, or as a federal right, where the plaintiffs have been adversely affected by the defendant's conduct of; disregard of federal safety rules, under the laws of the United States Department Of Health Education and Welfare as come under the Food Drug and Cosmetic Act of Congress, all constitutes a negligent liability, giving the Federal District Court Power to both hear, and to determine the entire controversy, even if relief is only based upon one grounds, and would be limited to less than the jurisdictional amount in controversy is satisfied in the complaint.

The Supreme Court in it's decision reported in the case of Conley V. Gibson[m],(see also exhibit[M], in addendum) it was held that a complaint should not be dismissed unless it appears beyond doubt, that no set of facts can be proven which would give relief. Therefore, the fact of liability alone can be proven that will give relief, and since no affirmative defense can, or has been pleaded by the defense; only controverted jurisdictional objections, but no specific denials by the defense, and attacks against the federal question, then the facts in the complaint have established a breach of duty, or a negligent act has been committed by the defendant, against the plaintiffs without any more question.

Under Rule 8(d), F.R.C.P., the defense may not have been permitted a responsive pleading, because of his objection under Rule 12(b), F.R.C.P., a motion for judgement on the pleadings, then the proceedings now! should be turned on the matter of extent to which the plaintiffs have suffered injury from the negligent act of prescribing provera to; an already complicated infectious condition in the plaintiff reproductive organs, and without taking a required pap smear test before the giving of the hormone drug, as his duty of care owed, and from such negligemce the plaintiffs have suffered untold injury, pain, more infection, and now possibly cancer in her female organs, while the marital home life has been diverted for life. The act by the defendant was a negligent omission, a gross negligent omission of a federal right, under a federal rule making authority as pertains to an experimental drug, while under exclusive control of federal regulations, makes this claim ripe for the relief sought. Because the federal responsibility in dispensing provera, was transferred to the defendant doctor for proper dispensing under federal safe labeling of experimental drug. However, the plaintiff's Federal Rights can never be transferred, this claim should not have been dismissed.

" BRIEF OF THE APPELLANT "

THE ARGUMENT SUMMARY:

As it now appears from the defense's response, or objection to the Court's jurisdiction over the subject matter in the complaint, the defense drew his conclusions from the non-federal part of the claim. However, any defect must appear on the face of the complaint(see rule 8(a) F.R.C.P.), which defines the setting forth of a claim for relief as; (1) A short and plain statement of the grounds upon which the Court's Jurisdiction depends. (2) A short plain statement of the claim showing that the pleader is entitled to relief. (3) A demand for judgement for the relief to which he deems himself entitled.

Therefore, it was premature for the Court to dismiss the claim from the short and plain statement on the face of the complaint, or from the defense's inconclusive evidence of non-factual inferences pleaded in the defense's motion to dismiss; or on the original jurisdictional grounds of the Federal Question, showing the plaintiff's entitlement for relief.

The subject matter did not get the opportunity to be heard properly from the outset, constituting prejudiciality affecting the recovery rights of the plaintiffs. For in the ruling made on the order to dismiss under motion, or if dismissal in any way leaned upon such conclusions of objections, in the defense's non-factual inferences, that the plaintiff's claim was an ordinary medical malpractice not depending on any federal question, and it is proven, or could be proven that the claim for relief demanded was recoverable under the federal question, then the judgement becomes reversible do to non-credible evidence, for if two conclusions of evidence of any material point were; or could be reached, it is non-credible. The defense first concluded that the claim was an ordinary medical malpractice suit, then he challenged the Court's Original jurisdiction on the federal question, (see exhibit[b], in addendum, par. 7, page 3), then he states that the alleged medical malpractice will not depend upon the validity, construction, or effect of federal law. He certainly could not have drawn this conclusion from the facts stated on the face of the claim, for not one time was any ordinary medical malpractice charge mentioned. The second conclusion that the court could have drawn a conclusion from is when the defense, stated that the claim did not depend upon any federal law, it may have, or could have depended upon a state law, but this he did not say; However, such a conclusion can be drawn from his statement, it was certainly implied. Therefore, if the Court's decision was based upon this fallacious, and inconclusive averment, it certainly is non-credible evidence for a dismissal of the plaintiff's valid claim, which did depend ultimately upon the federal question as seen in the face of the complaint for recovery.

" BRIEF OF THE APPELLANT "

STATEMENT OF FACTS RELATIVE TO JUDGEMENT ORDER:

The right of equal protection of the laws under the 14th Amendment, of the " equal protection clause," provides that; " No State shall... deny to any person within it's jurisdiction the equal protection of the laws." The 5th Amendment due process clause is applicable to the federal government as well as to states[d],(see table of statutes), under the stricter equal protection test where the statutory classification affects some fundamental right, or based on suspect criteria, the stricter test must be imposed, and it must also meet the traditional standard of reasonableness. In this case(suit), the fundamental rights, as well as the legal rights are certainly affected by the judgement order, and must be reviewed on constitutional grounds as well as statutory grounds, for the cause of action, as seen on the face of the complaint, is directed against the conduct of a defendant doctor, who under a federal statute[e],(under table of statutes)having to do with the federally regulated drug, Provera(medroxyprogesterone acetate), by violation of the F.D.A. rule making authority under labeling for safe administration, while regulated by federal safety rules, and causing injury to the plaintiffs by the effects of provera upon the plaintiff's prevailing health problem, that she was having upon her initial visit to the defendant's office on 9/5/73.

In seeking judicial review of administrative actions, the plaintiffs are able to demostrate injury in a substantial manner, to their legal protection under the Constitution and it's grant of General Federal Question, giving the plaintiffs standing to litigate because of their Federal Right being involved, as the claim did arise under or is covered by the United States Constitution, so there is no choice of law; for the determination of constitutionality and review of Administrative action is not limited, where the plaintiffs are suing for a breach of federal right of a duty of care, or for a tort, it can satisfy the Court, that the plaintiffs have standing to bring such suit, for the suit is brought by the plaintiffs who has been harmed by a charged wrong, and standing to sue is self evident.

In private litigation there is now very little difficulty in determining questions arising under, because the dispute over whether the Federal Courts can render Declaratory Judgements has been satisfactorily resolved. Therefore, most private litigation is of a nature clearly meeting the tests of justiciability, for the main body of the law on; " cases or controversies comes from cases raising questions of constitutionality of statutes, or cases seeking judicial review of Administrative action."

The very fact that the defense raised questions, and made adverse statements to an adverse effect; " that plaintiff's claim, did not depend upon the constitutional construction to warrant, relief." Is within

STATEMENT OF FACTS RELATIVE TO JUDGEMENT ORDER:

the Court's review, and certainly are controversies arising under, and with additional assertions; that the claim is simply an ordinary medical malpractice suit, not giving jurisdiction to the District Court, this is a fundamental and substantive challenge in an adverse context challenging the jurisdiction of the Court, and the constitutional validity of the claim; is a case in controversy. The defense attorney wants to challenge the validity of the claim, and the Court's jurisdiction, without, being subjected to the plaintiff's charges in the complaint. It is not left to any attorney to say that the Court's jurisdiction does not exist. The defendant has subjected himselfto the jurisdiction of the Court by his apperance, and admittance of the same; and to the Court's determination of the plaintiff's subject matter for review, under examination of the specific statute.[e],(under table of statutes page.

It is well understood that the Court's of the United States do not sit to decide questions in a vaccum, but only such real questions as arise in a case(suit) or controversy in the adverse, the only difference being; that controversy is less comprehensive until it is made more comprehensive. However, the controversy in this case has arisen.

The opposing side argues; that the claim," does not depend upon any construction of the constitutional laws of the United States, as regulated by the Food and Drug Administration," but that the rules and regulations of the F.D.A., are only directed at persons engaged in manufacture and distribution of drugs, and that the F.D.A.'s Rules and Regulations are not directed at, nor do they attempt to control or regulate the actions of Physicians in prescribing such drugs. The defense in the foregoing conclusions, has constructed a self made theory which is irrelevant, and is in complete disregard of the facts in the complaint, a theory that the claim attempts to regulate prescription drugs. However, the F.D.A. Regulations certainly attempts to regulate the actions of any doctor who dispenses the experimental drug; Provera relative to safe dispensation for this is their primary purpose. The claim mentions nothing relative to the control of prescriptions! Only, safe rules and regulations being breached, unless the non-federal part of the claim is is used for the facts, and this is probably what the defense used as their construction of such fallacious, assumptions. The facts remain unchallenged by the opposing parties as to the negligent charge against the defendant, as to the truth of the charge. Therefore, the real issue is the breach of duty owed by the defendant under federal law including the relief demanded.

Therefore, it must be determine by the Court, that as of the defend-

STATEMENT OF FACTS RELATIVE TO JUDGEMEMENT ORDER:

ant's appearance, original jurisdiction, or federal question now arises under. As to the subject matter, and the Court's jurisdiction over it, the review by the Court will decide this question according to law. The plaintiff's rebuttal found in the records, objects to the judgement order of dismissal, the plaintiffs argue that the cause of action was a breach of federally regulated right, which could only be resolved under this federal right for relief demanded, as hereinafter more fully appears. Therefore, if attempted resolution was made under another right, it would be a new and different cause for relief. However, the subject matter arises under the protection of the United States Constitution, with the protected authority of the U.S. Department Of Health Education and Welfare, with it's safety rule making authority of the Food Drug and Cosmetic Act., Title 21, which is in control; and preempted dominance, of experimental or hazardous drugs, is sufficient to show substantial rights of the plaintiff's for relief demanded.

Therefore, the dismissal was Prejudicial, because again, the subject matter is under a Federal Statute, being one for the U.S. Court's to resolve due to the dominant control by the F.D.A., of the subject matter, where Congress intended to occupy the field completely, for there are questions as to whether State Courts may award tort damages arising out of any frustration to national policy, by conflicting state determinations, or as to what determinations constitutes a doctor's regulations, or dispensing of oral contraceptives, outside of a Federal Right; which would defeat the objective of the Federal Statute. However, under the federal Statute, and regulations of any breach of duty of federal rights, while under Federal Court jurisdiction; it becomes clear, that the defendant's negligent act was a breach of duty owed, found specificly under the federal Statute, and F.D.A. Rules, not withstanding the fact that the defendant was also being paid for the safe care required, or owed, while federal rules and regulations were controlling factors.

The dismissal was Prejudicial again because it affected the substantial rights of the plaintiffs for relief demanded, for it's attempt to modify the cause of action, on the grounds that the cause of action as defined by the defense as a; common medical malpractice suit, is not the facts stated on the face of the federal complaint. The stated facts reveal a breach of duty of a federal right, that depends entirely upon that federal right for relief sought, due to the particular field which is dominantly controlled by Federal Regulation, any other right would change the amount sought in the prayers for relief.

" BRIEF OF THE APPELLANT "

STATEMENT OF FACTS RELATIVE TO JUDGEMENT ORDER:

The dismissal was prejudicial, because the plaintiff's federal rights are involved and affected, for the plaintiff's complaint involves a breach of duty owed under the federal statute, because of the drugs experimental field study control, and in this case, federal law alone will be applied to that issue, where the dominancy of the field is under federal control the State Courts don't want the case. This follows from the Supremacy Clause of the U.S. Constitution(article 6), that provides; " This Constitution and the Laws of the United States which shall be made in pursuance thereof.... shall be the Supreme Law of the land; and the Judge in every State shall be bound Thereby." Federal Law alone is applied to any issue arising in the field in which federal power is exclusive, such as; Admiralty, Bankruptcy, Patients, Military and Foreign Affairs, National Banking, and Foreign Commerce, etc., and likewise in those fields which Congress has, " Preempted" that is; most of commerce, then the granting of relief ultimately depends upon the construction of the constitutional laws or treaties of the United States.

THE DENIAL OF AN ORAL MOTION:

The plaintiffs filed at Utica, N.Y., a notice of motion for a hearing returnable on April 26, 1976, at 10:00 am, it was not an affidavit, but was an exception to process service of summons, given to the U.S. Marshal's Office at Utica, N.Y., February 23, 1976. The presiding Judge did not have any answer from the defendant, the defendant's answer was received on April 15, 1976.(see exhibit "C" in addendum), and it was not until May 5, 1976, that the plaintiffs discovered that the defendant's attorney had previously filed with the Clerk of the Court at Utica, N.Y.. This discovered information by the plaintiffs came by way of; an affidavit from the defense attorney; at the time was in opposition to the plaintiff's affidavit made on May 5, 1976, for default Judgement to be entered against the defendant,(see exhibit"A" in addendum), which is the answer received by the plaintiffs from the defense attorney, to show that he had timely filed his answer with the Clerk at Utica, N.Y.. However, at the April 26, 1976, hearing the plaintiffs wanted to show diligence on their part relative to the filing of the summons and complaint. But to the contrary the Judge did not allow the plaintiffs to make a speaking motion in open court. However, since the plaintiffs are not aggrieved over the service of the summons or it's processing, argument is waived. But exception is taken to the ruling made by the judge on the denial of the speaking motion attempted to be made on April 26, 1976. The action was commenced on February 10, refiled on February 23, and given to the U.S. Marshal's Office on February 23, in the same year

" BRIEF OF THE APPELLANT "

DENIAL OF AN ORAL MOTION:

1976, of the Utica, Court Hearing. The denial of the speaking motion becomes issue for review, for it is now quite clear that any common law rule against speakimg motions is ended, and that the Court is not confined to the pleadings and motions in ruling. but may consider evidentiary matter presented by affidavit or otherwise, and it has always been the rule where jurisdiction is challenged or dilatory defense is being raised.

All motions except those made in writing, and are to state with particularity the grounds thereof, and set forth the relief or order sought. But this was denied to the plaintiffs.(see rule 7(b) F.R.C.P., that gives authorization for a motion to be made during a hearing not in writing, and this was not granted to the plaintiffs.

Amendments to those rules of the lower Court, made in 1948 provided that where relief can be granted, or moves for judgement on the pleadings, and matters outside the pleadings are presented to and not excluded by the Court, the motion is to be treated as if it were a motion for summary judgement under Rule 56, F.R.C.P., relief could be granted in yhis case. Therefore, the plaintiff's concern here is; why didn't the lower Court follow these rules? The defense moved for a motion or judgement on the complaint, yet the motion was not treated as if it were a motion for summary judgement, but was a dismissal. The claim should not have been dismissed.(see evidence of exhibits "M" - "1" in appendix addendum).

STATEMENT OF PRECISE RELIEF SOUGHT:

1. Plaintiffs seek affirmation of money demanded in the complaint or prayers of relief, on the grounds of facts; that the defense has not made any specific denial of the charges.

2. Relative to the Court's jurisdiction of the subject matter; whatever relief favorable to the plaintiff's cause by the Appeals Court as it deems as just in this case.

3. In case of remand; Plaintiffs petitions the Appeals Court to remand under Rule 57, F.R.C.P., Title 28 U.S.C. 2201 and pursuant to General Rule 12, of U.S. District Court Of The Northern Disterict Of New York: The Demand for trial by Jury, with the remedy of a Declaratory Judgement favorable to the plaintiffs on the grounds of Negligence, Not Denied, as provided under Federal Law; Rules 38 and 39, F.R.C.P., in the event the Court does not find relief otherwise.

REPRESENTATIVE: (John L. Grady)

UNITED STATES COURT OF APPEALS SECOND CIRCUIT

C. A. TEMP: NO. T-6079

MR. JOHN L. GRADY
MRS. FATIMA GRADY
PLAINTIFFS

VS.

DR. RODERICK A. McLEAN
DEFENDANT

APPEAL: PETITION FOR REVIEW

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT

OF NEW YORK

BRIEF OF APPELLANT: APPENDIX

REPRESENTATIVE: (John L. Grady)

APPENDIX OF BRIEF

PAGE:

DIST/OFFICE	DOCKET YR.	DOCKET NUMBER	MO.	DAY	YEAR	J	N/S	O	R	23	$	OTHER	NUMBER	DEM.	YR.	NUMBER
206	76	-CV-58	02	10	76	3	360	1			9999			P		✓

PLAINTIFFS	DEFENDANTS
GRADY, JOHN L., GRADY, FATIMA	McLEAN, RODERICK A., Dr., Gynecologist of Syracuse, N.Y.

APPENDIX
PAGE 1

CAUSE Malpractice

76-CV- 58

ATTORNEYS

John L. Grady, Representative
141 Bishop Ave.
Syracuse, N.Y.

Martin, Ganotis, Amsler & Brown, Esq
499 S. Warren St.
Syracuse, N. Y. 13202

☐ CHECK HERE IF CASE WAS FILED IN FORMA PAUPERIS	FILING FEES PAID			STATISTICAL CARDS	
	DATE	RECEIPT NUMBER	C.D. NUMBER	CARD	DATE MAILED
	2/10/76	47418	65	JS-5	
	5/17/76	49324	54 and 92	JS-6	

76-CV-58

DATE 1976	NR.	PROCEEDINGS
Feb. 10	1	Filed complaint-issued summons-orig. & 1 copy & delivered to the Marshal for service
Feb. 23	2	Filed amended complaint
Mar. 30	3	Filed Petition to Practice
Apr. 1	4	Filed summons served 3/31/76 on Dr. Roderick A. McLean, MD
Apr. 6	5	Filed Notice of Motion returnable Apr. 26, 1976, at Utica & Motion for Exception of Process of Service of Summons
Apr. 19	6	Filed Notice of Appearance
Apr.19	7	Filed Notice of Motion returnable May 10, 1976 at Syracuse & affidavit of Edward J. Amsler
Apr. 23	8	Filed amended notice of motion
Apr. 22	9	Filed Notice of Motion, returnable May , 1976 & related papers
Apr. 26	10	Filed Note of Issue for September 1976 term of court at Syracuse-Jury
Apr. 26		Motion for exception to process service of summons-Adjourned to Syracuse on May 10, 1976
Apr. 30	11	Filed Notice of Motion for Default Judgment, returnable May 10, 1976, & Affidavit of John L. Grady
May 4	12	Filed Notice of Motion, returnable May 10, 1976 at Syracuse for an Order denying any application for a special appearance & Affidavit of John L. Grady
May 5	13	Filed Notice of Motion, returnable May 10, 1976 at Syracuse to Strike Affidavit of Defense
May 5	14	Filed Notice of Motion, returnable May 10, 1976 to Strike plaintiffs' of issue pursuant to Rule 12(f) F.R. C. P. & Affidavit of Edward J. Amsler
May 5	15	Filed Affidavit in Opposition by Edward J. Amsler
May 7	16	Filed Affidavit in opposition
May 10		Motion to Dismiss-Edward Amsler admitted for the purpose of arguing the motion. Motion to dismiss granted without prejudice.
May 13	17	Filed Order of Judge Port (5/12/76) that the motion to dismiss is gran and that the action is dismissed without prejudice for lack of subjec matter jurisdiction,etc.
May 13	18	Filed Judgment
May 17	19	Filed Notice of Appeal
May 26	20	Filed copy of Notice of Appellee of Partial Transcript is ordered.

"I certify that
This is a true copy

Attest 5/27/76

J. R. SCULLY
Clerk, U.S. District Court

By: W. Murphy
Deputy

APPENDIX
PAGE 2

UNITED STATES DISTRICT COURT
OFFICE OF THE CLERK
NORTHERN DISTRICT OF NEW YORK
UTICA, N. Y. 13503

JOSEPH R. SCULLY
CLERK

April 19, 1976

Martin, Ganotis, Amsler & Brown
Counsellors at Law
499 S. Warren Street
Syracuse, New York 13202

ATTENTION: Edward J. Amsler, Esq.

Re: Grady v. McLean
76-CV-58

Dear Sir:

Receipt is hereby acknowledged of yours of April 14, 1976 enclosing original notice of appearance in the above entitled action, together with notice of motion and affidavit and other related papers.

Please be advised that same have been filed in this office under even date.

Very truly yours,

J. R. SCULLY, CLERK

BY James K. Evans
James K. Evans
Chief Deputy Clerk

JKE:cd

THIS LETTER RECEIVED BY PLAINTIFFS ON MAY 5, 1976, ACCOMPANIED BY EXHIBIT A"

Exhibit A

APPENDIX
PAGE # 3

"I certify that
This is a true copy

Attest 5/14/76

J. R. SCULLY
Clerk, U.S. District Court

By: W. Murphy
Deputy

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

MR. JOHN L. GRADY,
MRS. FATIMA GRADY,

Plaintiffs

vs.

DR. RODERICK A. McLEAN,

Defendant.

76-CV-58

EDMUND PORT, Judge

ORDER

The defendant in the above-entitled action, having moved to dismiss the action for lack of subject matter jurisdiction and the court having heard the parties and having dictated its decision on the record, it is

ORDERED, that the motion be and the same hereby is granted; and it is further

ORDERED, that the action be and the same hereby is dismissed without prejudice for lack of subject matter jurisdiction; and it is further

ORDERED, that the Clerk is directed to serve a certified copy of this Order upon the plaintiffs herein and the attorneys for the defendant.

Edmund Port
Senior United States District Judge

Dated: May 12, 1976
Auburn, New York

76-CV-58

United States District Court

NORTHERN DISTRICT OF NEW YORK

MR. JOHN L. GRADY,
MRS. FATIMA GRADY,

Plaintiffs

vs.

DR. RODERICK A. McLEAN,

Defendant.

O R D E R

PORT, JULGE

76-7298

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

C.A. TEMP. NO. T-6079

MR. JOHN L. GRADY,
MRS. FATIMA GRADY,
Plaintiffs

VS.

DR. RODERICK A. McLEAN
Defendant.

APPELLANT'S STATEMENT OF PROOF OF SERVICE ON OTHER PARTY

---

1. Please be notified that on June 23, 1976, Representative for the plaintiffs Mr. John L. Grady did by certified mail service, serve on Edward J. Amsler Attorney for the defendant, Dr. Roderick A. McLean, two copies of the appellant's briefs containing 15 numbered pages and 3 un-numbered pages; also served one copy of the separate volume of the brief appendix containing 3 numbered pages or six sheets; in addition one copy of the separate exhibits of brief of appendix addendum, the third volume separately submitted, containing the balance of numbered pages of the brief of the appendix numbered from 4 to 10 inclusive, with 32 sheets.

2. Two copies of the brief is served on counsel, and one copy of each of the other two volumes of the appendix, and appendix with exhibits of the addendum is served on counsel totaling 4 volumes in all.

Dated: June 23, 1976.

Representative: John L. Grady

144 Bishop Ave. Syracuse, N.Y. 13207

No. 655347

RECEIPT FOR CERTIFIED MAIL—30¢ (plus postage)

SENT TO
Edward J. Amsler Attorney At Law

STREET AND NO.
499 So. Warren St.

P.O., STATE AND ZIP CODE
Syracuse, N.Y. 13202

POSTMARK OR DATE
U.S.P.O. N.Y. JUN 23 1976

OPTIONAL SERVICES FOR ADDITIONAL FEES

RETURN RECEIPT SERVICES
1. Shows to whom and date delivered ..... 25¢
With delivery to addressee only ..... 65¢
2. Shows to whom, date and where delivered .. 35¢
With delivery to addressee only ..... 85¢

DELIVER TO ADDRESSEE ONLY ..... 50¢

SPECIAL DELIVERY (extra fee required) .....

PS Form 3800 Apr. 1971

NO INSURANCE COVERAGE PROVIDED—NOT FOR INTERNATIONAL MAIL

(See other side)

☆ GPO : 1974 O - 551-454

Proof of service of motion paper on opposing party to appeals Court

No. 184038

RECEIPT FOR CERTIFIED MAIL

SENT TO
Edward J. Amsler Attorney

STREET AND NO.
499 So. Warren St.

P.O., STATE AND ZIP CODE
Syracuse, N.Y. 13202

POST MARK OR DATE
SYRACUSE, N.Y. JUN 23 1976 USP

OPTIONAL SERVICES FOR ADDITIONAL FEES

RETURN RECEIPT SERVICES
1. Shows to whom and date delivered With restricted delivery
2. Shows to whom, date and where delivered With restricted delivery

CONSULT POSTMASTER FOR FEES

RESTRICTED DELIVERY

SPECIAL DELIVERY (extra fee required)

PS Form Jan. 1976 3800 NO INSURANCE COVERAGE PROVIDED— NOT FOR INTERNATIONAL MAIL (See other side)

☆ GPO: 1975—O-591-452

opposing side

REGISTERED NO. 4482

POSTMARK OF
SYRACUSE, N.Y. JUN 23 1976

Value	$ A.C.V.	Special Delivery	$
Reg. Fee	$ 1.25	Return Receipt	$ .20
Handling Charge	$	Restricted Delivery	$
Postage	$ 4.03	☒ AIRMAIL	

POSTMASTER (By) [illegible]

MAILING OFFICE

FROM John Crary
141 Bissell Ave
13207

TO Clerk U.S. Court
of Appeals U.S. Court
House Foley Square
N.Y. N.Y.

☆ GPO 1974 503 269

appeals Court

Proof of Service of Briefs
on opposing side